# The National Academies of SCIENCES • ENGINEERING • MEDICINE

# Standing Committee on Emerging Infectious Diseases and 21<sup>st</sup> Century Health Threats

## Workshop on Allocation of COVID-19 Monoclonal Antibody Therapies and Other Novel Therapeutics Final Agenda

December 16-17, 2020 10:00 a.m. – 2:00 p.m. ET Zoom Webinar

# Workshop Objectives

- Discuss key considerations for assisting decision makers in their efforts to equitably allocate COVID-19 monoclonal antibody therapies and other novel therapeutics at the state and local levels
- Examine related key issues such as barriers to access, particularly for populations at high risk for serious COVID-19-related outcomes, administration capacity, cost, and data collection and reporting

# Day 1 – December 16, 2020

## SESSION I: Welcome and Opening Remarks to Day 1

10:05 a.m. Welcome and Meeting Objectives Harvey Fineberg, Standing Committee Chair President Gordon and Betty Moore Foundation

10:10 a.m. **Opening Remarks** Victor Dzau President National Academy of Medicine

#### 10:15 a.m. **Opening Remarks** *Robert Kadlec* Assistant Secretary for Preparedness and Response Department of Health and Human Services

## **SESSION II: Overview and Background**

<u>Session Moderator</u>: *Kent Kester, Standing Committee Member* <u>Session Objectives</u>: To provide a shared understanding of the current state of efforts around the allocation of COVID-19 monoclonal antibody therapies from the policy-level perspective.

## 10:20 a.m. **Brief Overview of COVID-19 Monoclonal Antibody Allocation Considerations at the Federal Level** John Redd Chief Medical Officer Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services Right Patient, Right Time, Right Place: A Critical Challenge of COVID-19 10:35 a.m. **Monoclonal Antibodies** Marta Wosinska Consulting Professor Deputy Director, Policy Duke-Margolis Center for Health Policy 10:50 a.m. **Other Policy-Level Perspectives** Michael Ganio Senior Director, Pharmacy Practice and Quality Center on Medication Safety and Quality American Society of Health-System Pharmacists Michael Wargo Vice President of Emergency Preparedness HCA Healthcare Acting Chair U.S. Healthcare and Public Health Sector Coordinating Council Mark Jarrett Senior Vice President and Chief Quality Officer Northwell Health

#### 11:15 a.m. Moderated Discussion with Panelists

11:45 a.m. Lunch / Break

## **SESSION III: On-the-Ground Perspectives**

Session Moderator: John Hick, Standing Committee Member

<u>Session Objectives</u>: To discuss the different frameworks being used to allocate COVID-19 monoclonal antibody therapies and other novel therapeutics at the state and local levels and to discuss first-hand experiences, challenges, successes, and lessons learned.

#### 12:15 p.m. State and Local Stakeholders

*Jeff Gumprecht* Associate Professor of Infectious Disease Mount Sinai Health System

*Eric France* Chief Medical Officer Colorado Department of Public Health and Environment

Mohammad Kharbat Vice President Pharmacy Services and Health Research SSM Health—Wisconsin Region

Megan Klatt Infectious Diseases Pharmacy Resident University of Michigan School of Medicine

*Trisha Jordan* Director of Pharmacy Clinical Services The Ohio State University Wexner Medical Center

Lawrence Madoff Medical Director Bureau of Infectious Disease and Laboratory Sciences Massachusetts Department of Public Health

John Sanders Head, Infectious Disease Section Wake Forest Baptist Health System

*Emily Sydnor Spivak* Associate Professor of Medicine Division of Infectious Diseases University of Utah

#### 1:00 p.m. Moderated Discussion with Panelists

## SESSION IV: Day 1 Wrap Up

1:45 p.m. Wrap Up and Summarize Day 1 Harvey Fineberg, Standing Committee Chair President Gordon and Betty Moore Foundation

2:00 p.m. Adjourn Day 1

## Day 2 - December 17, 2020

## **SESSION V: Welcome to Day 2**

10:00 a.m. Welcome and Introduction to Day 2 Harvey Fineberg, Standing Committee Chair President Gordon and Betty Moore Foundation

## **SESSION VI: Access and Equity Considerations**

<u>Session Moderator</u>: *Alta Charo, Standing Committee Member* <u>Session Objectives</u>: To discuss the specific considerations related to key issues of access and equity, particularly for marginalized populations.

10:05 a.m. Issues of Access and Equity

Robert Goldstein Medical Director Transgender Health Program Massachusetts General Hospital

*Keith Boell* Chief Quality Officer for Population Initiatives Geisinger Health System

*Christian Ramers* Medical Director, Laura Rodriguez Research Institute Chief, Population Health Director, Graduate Medical Education Family Health Centers of San Diego

Andrew Shuman Associate Professor, Division of Head and Neck Oncology University of Michigan Health System Co-Chief, Clinical Ethics Service Center for Bioethics and Social Sciences in Medicine University of Michigan Medical School

Abigail Echo-Hawk (Citizen of the Pawnee Nation) Director Urban Indian Health Institute Chief Research Officer Seattle Indian Health Board

Nneka Sederstrom Director Clinical Ethics Department Children's Hospitals and Clinics of Minnesota

*Robyn Stone* Senior Vice President for Research LeadingAge

*Connie Sullivan* President and CEO National Home Infusion Association

*Douglas White* Vice Chair and Professor of Critical Care Medicine, UPMC Endowed Chair for Ethics in Critical Care Medicine Director, Program on Ethics and Decision Making in Critical Illness University of Pittsburgh School of Medicine

*Govind Persad* Assistant Professor Sturm College of Law University of Denver

#### 11:00 a.m. Moderated Discussion with Panelists

12:00 p.m. Lunch / Break

## **SESSION VII: Other Considerations**

<u>Session Moderator</u>: *Donald Berwick, Standing Committee Member* <u>Session Objectives</u>: To discuss the other considerations surrounding the implementation of allocating COVID-19 monoclonal antibody therapies and other novel therapeutics.

#### 12:30 p.m. Key Consideration: Cost

Marianne Hamilton Lopez Research Director of Value-Based Payment Reform Duke-Margolis Center for Health Policy

Anna Kaltenboeck, Senior Health Economist and Program Director Drug Pricing Lab Center for Health Policy and Outcomes Memorial Sloan Kettering Cancer Center

Brian Nyquist President and CEO National Infusion Center Association

#### 12:45 p.m. Key Consideration: Manufacturing Capacity to Scale Up Supply

Andrew Adams Vice President New Therapeutic Modalities Eli Lilly

Ronald Cobb Chief Scientific Officer Ology Bioservices, Inc.

#### 12:55 p.m. Key Consideration: Other Issues

**Evidence Generation / Data Considerations** Sameer Awsare Associate Executive Director The Permanente Medical Group

Natalie Dean Assistant Professor of Biostatics University of Florida

#### **Global and International Issues**

Mark Feinberg President and CEO International AIDS Vaccine Initiative (IAVI) *Charlotte Taylor* Acting Director, Therapeutics Taskforce United Kingdom Department of Health and Social Care

## 1:20 p.m. Moderated Discussion with Panelists

# SESSION VIII: Day 2 Wrap Up

1:45 p.m. Closing Remarks Harvey Fineberg, Standing Committee Chair President Gordon and Betty Moore Foundation

2:00 p.m. Adjourn Day 2